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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/561,162

12/16/2005

Stanley Nattel

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1989

7590

12/31/2008

Louis Tessier
PO Box 54029
Town of Mount Royal, QC H3P 3H4
CANADA

EXAMINER

GEMBEH, SHIRLEY V

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

12/31/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/561,162	Applicant(s) NATTEL, STANLEY	
	Examiner SHIRLEY V. GEMBEH	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11, 12 and 14-26 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 and 15-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9, 11, 12 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-9, 11, 12 and 14-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The response filed on 10/16/08 has been entered.
2. Applicant's argument filed 10/16/08 has been fully considered but they are not deemed to be persuasive.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 1-9, 11-12 and 14-26 are pending, claims 9, 11-12 and 14 are rejected in this office action. Claims 1-2, 4-8, 15-26 are withdrawn.
5. Claim 3 is objected to as an improper dependent claim since it depends on withdrawn claim, which is further improperly identified as "original" versus "withdrawn", and therefore, is not in accordance with Rule 1.121.
6. The rejection of claims 9 and 14 under 35 U.S.C. 112, second paragraph, as being vague is withdrawn due to the amendment of the claims.
7. The rejection of claim 12 under 35 U.S.C. 112, second paragraph, as being vague and indefinite is withdrawn due to the amendment of the claims.

8. The rejection of claims 9, 11-12 and 14 under 35 U.S.C. 112, first paragraph, as is withdrawn due to the amendment of the claims.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 depend from a cancelled claim, and therefore it is not clear what the limitations of the cancelled claim is.

10. Claims 9, 11 and 14 stand rejected under 35 U.S.C. 102(a) as being anticipated by West et al., (2002) for the reasons made of record in Paper No. 20080416 and as follows.

Applicant argues that amended claim 9 recites "a method of reducing atrial fibrillation by substrate modification comprising the step of administering to a mammal in need thereof an amount of a statin drug therapeutically effective for reducing the incidence of atrial fibrillation in the mammal," and that West does not teach prevention of AF.

Art Unit: 1618

In response, all that is required in the claim is the administration of an effective amount of a statin drug that reasonably reduces the incidence of AF due to the inherent properties of the drug, simvastatin.

Careful consideration has been given to the remarks but found not persuasive.

11. Claims 9, 11-12 and 14 stand rejected under 35 U.S.C. 103(a) as being unpatentable over West et al. (2002) in view of Hanson US 6,376,242 taken with Ullah et al. (US 6,235,311), for the reasons made of record in Paper No. 20080416 and as follows.

Applicant argues that neither West et al, Hanson nor Ullah teaches the claim limitations of instant claims 9, 11-12 and 14.

As provisionally made of record, West teaches administering a statin (pravastatin or simvastatin) to patients with atrial fibrillation wherein the patient is a mammal/human (see abstract, introduction, page 2515 under results and prognostic index and discussion).

However, West only fails to teach the dosage administered, as required by instant claim 12. Therefore Hanson was introduced.

Hanson teaches administering statins such as simvastatin (claim 11) to humans and mammals suffering from atrial fibrillation and cardiovascular disease. See col. 3, line 50, col. 10, lines 56—60, col. 12, line 64 and col. col. 35, lines 37-40. Hanson further teaches the drugs are administered at 0.01-30 mg/kg/day, see col. 42, lines 15-

Art Unit: 1618

16. However, Hanson is silent in the teaching of reducing the incidence of AF, therefore Ullah was introduced to show that these drugs are known in the art to reduce AF.

Ullah et al. teach administering a statin (simvastatin) to reduce the risk of or treating cardiovascular event or disease including coronary artery disease. See col. 1, lines 58-65 and col. 2, lines 48-50. It is understood by the Examiner that AF results in cardiovascular event such as stroke, heart attack.

As can be seen, all the references cited by the Examiner would have resulted in the claim invention at the time the claim invention was made. Thus the invention was prima facie obvious at the time of invention.

12. No claim is allowed

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. V. G./
Examiner, Art Unit 1618
12/17/08

/Robert C. Hayes/
Primary Examiner, Art Unit 1649